

REMARKS

The above-identified patent application has been reviewed in light of the Non-Final Office Action dated April 10, 2007. No claims have been amended or canceled by this paper. Accordingly, Claims 1-15 and 18 are now pending. As set forth herein, reconsideration and withdrawal of the rejections of the claims are respectfully requested.

Claims 1-15 and 18 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,544,234 to Gabriel. ("Gabriel"). Claim 9 stands rejected under 35 U.S.C. §103(a) as being obvious over Gabriel. However, all of the claimed elements cannot be found in the Gabriel reference. Accordingly, reconsideration and withdrawal of the rejections of the claims as anticipated by or obvious in view of the Gabriel reference are respectfully requested.

The present invention is generally directed to an injection device with a retractable needle. In particular, as set forth in the pending claims, the injection device features an inner housing that is configured to perform a number of different functions during operation and use of the injection device. As will be explained in detail herein, the Gabriel reference does not teach, suggest or describe an injection device with an inner housing as set forth in the pending claims. Moreover, the Gabriel reference does not teach, suggest or describe an injection device with components configured to operate in the same way as the claimed invention.

The Gabriel reference is generally directed to a single use, autoinjector device. As shown in Fig. 3, an inward radial force  $F$  is applied to member 74 to initiate the injection. The inward movement of member 74 causes an inward movement of resilient detent member 84, which is part of displacement member 36. This disengages displacement member 36 from the housing portion 60, at recess 82. As a result, cocked spring 94 is released, which causes displacement member 36 and ejection member 92 to move forward together. The displacement member 36 and the ejection member 92 move together because, at this point in the injection, they are coupled together by lug 100 in recess 102. The action of the displacement member 36 on the flange 20 of the syringe barrel moves the needle 18 forward into the subcutaneous tissue of the patient to a depth determined by the abutment of collar shaped segment 34 against shoulder 54 (see Fig. 5). Just before the maximum depth of insertion is reached, as shown in Fig. 4, the

injection is triggered when lug (detent member) 100 is deflected radially inward by projection 70 so that displacement member 36 and ejection member 92 are no longer coupled together. At this stage of the injection, the ejection member 92 is free to move forward, under the action of the spring 94, so that axial gap 110 closes, and the ejection member 92 abuts pressure plate 26 of the syringe 12 in order to deliver the injection.

After the entire dose has been delivered from the syringe 12, the injection is complete. Unlike the claimed invention, the needle 18 associated with the device disclosed by Gabriel is not designed to retract nor is it able to retract after an injection has been delivered. As shown in Fig. 5 of Gabriel, the pressure plate 26 of the syringe 12 abuts the injection member, which prevents the syringe 12 from retracting into the interior of the injection device 10. In order to protect a user from the exposed needle 18, the Gabriel device needs a needle protection sleeve 46. Referring to Fig. 15, when the needle 18 is pulled out of the subcutaneous tissue, a needle protection sleeve 46 is displaced by its compression spring 56 in order to conceal the needle 18.

In applying Gabriel to the claimed invention, the Office Action equates the ejection member 92 of Gabriel with the inner housing of the claimed invention. While the ejection member 92 of Gabriel operates to engage the plunger and move the plunger axially to expel medicament through the needle, the ejection member is not an inner housing that is intermediate the outer housing and the barrel and plunger. Moreover, the ejection member 92 does not include any structure or perform any function with respect to contacting or engaging the barrel of a syringe to move the barrel and a plunger axially, or to allowing the plunger and barrel to retract by acting on neither the plunger nor the barrel. Additionally, the Office Action cites elements 96 and 100 of Gabriel as being equivalent to the inner housing of the present invention. However, it is noted that element 96 is an annular shoulder and element 100 is a lug, neither of which may be considered equivalent to the inner housing of the claimed invention.

With respect to at least pending Claim 1, Gabriel does not teach, suggest or describe an inner housing intermediate the outer housing and the barrel and plunger that is moveable by the energy source and that is in contact with and acts on the barrel such that, in use, the plunger and barrel move axially so as to move at least part of the needle out of the outer housing. It is

observed that in the initial phase of the injection, the Gabriel device includes two components (ejection member 92 and displacement member 36), which are coupled together to engage the barrel of the syringe. The two components move either together, or independently of one another, depending on the stage of the injection. (Gabriel, column 4 lines 12-18) In contrast, the claimed invention recites a unitary inner housing that accomplishes this and other functions. As mentioned on page 3, lines 24-27 of the present application, it is advantageous that “the overall complexity of the injection device is significantly reduced by both of these requirements being effected by one component, namely, the inner housing.”

Gabriel also does not describe a second mode in which the inner housing is in contact with and acts on the plunger to move the plunger axially but not the barrel so as to expel medicament through the needle. Instead, according to Gabriel, after the needle has penetrated the skin, the ejection member 92 decouples from the displacement member 36. At this point, a proximal end face 112 of the ejection member 92 presses against and displaces the pressure plate 26 of the plunger to cause medicament to be expelled through the needle 18. (Gabriel, column 4, lines 43-49). The ejection member 92, acting by itself, is not equivalent to the inner housing as recited by the claimed invention. Additionally, it is noted that the Gabriel device includes a gap 110 between end 112 and the pressure plate 26. (Gabriel, column 4, lines 18-25, Fig. 4). In contrast, the equivalent parts in the claimed invention are always in contact with one another.

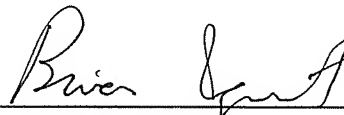
Gabriel also does not teach, suggest or describe a third mode in which the inner housing acts on neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract into the outer housing. In addition, the Gabriel device does not feature a needle that can be retracted into the outer housing and requires that the patient pull the needle out of the subcutaneous tissue himself, instead of the needle automatically retracting. (Gabriel, column 5, lines 28-34). As mentioned above, once the patient has pulled the needle of the Gabriel device out of his tissue, a needle protection sleeve 46 is displaced forward to cover the exposed needle 18. Therefore, for at least these reasons, the pending claims are not anticipated by or obvious in view of Gabriel and the rejections of the claims should be reconsidered and withdrawn.

With respect to independent Claim 18, as previously noted with respect to Claim 1, Gabriel does not teach, suggest or describe an inner housing intermediate the outer housing and the barrel and plunger. In addition, Gabriel does not discuss engaging the barrel with and the inner housing and moving the barrel and plunger axially in a first direction by means of the inner housing. Instead, the ejection member of Gabriel acts on only the plunger, and the displacement member coupled to the ejection member acts on the barrel. Moreover, the ejection member of Gabriel does not comprise an inner housing. Similarly, Gabriel does not describe an inner housing that engages the plunger to move the plunger axially in the first direction. The Gabriel reference also does not teach, suggest or describe a device having an inner housing that, after causing medicament to be expelled through the needle, disengages from the barrel and the plunger, and retracting the needle into its biased position wholly inside the outer housing. Therefore, the rejection of Claim 18 should be reconsidered and withdrawn.

As discussed herein, the Gabriel reference does not teach, suggest or describe each and every element set forth in the pending claims. Accordingly, early notification of allowance is respectfully requested. The Examiner is invited to contact the undersigned by telephone if doing so would expedite resolution of this case.

Respectfully submitted,

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